

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESAL PRICE LITIGATION

MDL No. 1456

THIS DOCUMENT RELATES TO
ALL MASSACHUSETTS AND NON-
MASSACHUSETTS CLASS ACTIONS
CONCERNING ASTRAZENECA
CLASSES 2 & 3

CIVIL ACTION: 01-CV-12257-PBS

Judge Patti B. Saris

**NOTICE OF FILING REVISED SETTLEMENT AGREEMENTS, SUPPORTING
MATERIAL, AND PROPOSED SCHEDULE FOR ALL SETTLEMENT EVENTS
RELATED TO SETTLEMENT OF MASSACHUSETTS AND NON-
MASSACHUSETTS ASTRAZENECA CLASSES TWO AND THREE**

Class Plaintiffs hereby give notice of filing of the Revised Settlement Agreement and Release of AstraZeneca Related to Non-Massachusetts Classes 2 and 3 and the Revised Settlement Agreement and Release of AstraZeneca Related to Massachusetts Classes 2 and 3 (collectively, the “Revised Settlement Agreements”), both accompanied by revised exhibits as appropriate. Each of the Revised Settlement Agreements has been filed separately herewith. The agreements have been revised consistent with the Court’s comments during the preliminary approval hearing on Monday, July 12, 2010, as discussed in more detail below.¹ The revisions apply to both the Massachusetts and Non-Massachusetts agreements equally, except as indicated.

¹ Class Counsel has not re-filed the Joint Motion for Entry of an Order Preliminarily Approving the Non-Massachusetts Settlement [Docket No. 7141] and the Massachusetts Settlement [Docket No. 7144] or the Memoranda in Support of those Motions [Docket Nos. 7142 and 7145 respectively.] Arguments made in favor of granting preliminary approval to the Settlement Agreements apply equally to the Revised Settlement Agreements.

Class Plaintiffs also submit a proposed schedule of events related to the settlements for the Court's review and approval.

A. Pulmicort Respules®

Pulmicort Respules® ("Pulmicort") is an inhaled drug used primarily to treat pediatric asthma. The original versions of both Settlement Agreements included a release and reimbursement to class members for payments made for Pulmicort because Pulmicort was included in the Court's class certification order related to claims under M.G.L. c 93A by classes 2 and 3 against AstraZeneca.

Pursuant to the discussion at the July 12, 2010 hearing, AstraZeneca moved for entry of an order granting judgment and dismissing all claims asserted by Massachusetts Class 2 and 3 under Mass.G.L. c93A with respect to Pulmicort. On August 4, 2010 the Court entered such an order. [Docket No. 7210]. The Court's order entering judgment and dismissing claims related to Pulimcort in the Massachusetts case formalized what had already been recognized by the litigating parties and by the Court at trial.

With respect to non-Massachusetts claims, the Court indicated in the July 12, 2010 hearing that the Court had not intended to certify national classes related to Pulmicort in its Sept. 26, 2008 Memorandum and Order. Accordingly, the Revised Proposed Final Approval Order attached as Exhibit J to the Non-Massachusetts Settlement has been revised to include the following paragraph:

The Court confirms that Zoladex® was the only AstraZeneca drug as to which class claims were certified in the Court's Sept. 26, 2008 Memorandum and Order certifying Non-Massachusetts Classes 2 and 3. The Court did not certify Non-Massachusetts class claims with respect to Pulmicort Respules® or any other AstraZeneca drug.

See Revised Settlement Agreement Related to Non-Massachusetts Classes 2 and 3, Ex. J ¶ 8.

The Revised Settlement Agreements do not include a release related to Pulmicort, and no funds are allocated to consumers or TPPs related to payments for Pulmicort. The Revised Settlement Agreements release claims only with respect to Zoladex and compensate class members only based upon their expenditures related to Zoladex.

B. Revised Consumer Notice Program

At the July 12, 2010 hearing, the Court requested that Katherine Kinsella, of Kinsella Media, provide an affidavit related to the proposed notice program. The Court was concerned with the utilization of national print publications and directed Class Counsel to have Kinsella Media provide a media plan that maximized use of media that Kinsella, in her experience in AWP settlements as well as in other cases, found to be most effective at prompting consumer response. The Affidavit of Katherine Kinsella attesting to the submission of a Revised Media Plan (Massachusetts' Settlement Agreement Ex D, Non-Massachusetts' Settlement Ex. G) and the support for components of the Revised Media Plan is attached hereto as Exhibit A.

Consistent with the Court's order granting judgment and dismissing claims related to Pulmicort, Kinsella Media has removed those elements of the original notice plan designed to reach purchasers of Pulmicort. In addition, Kinsella Media has conducted a very in-depth analysis of media vehicles best suited to reach the target audience of Zoladex users. In creating the Revised Consumer Notice Program Kinsella utilized both the process of "indexing" to analyze how prostate prescription drug users consume particular media, as well as Kinsella Media's extensive prior experience with the types of

media that traditionally drive responses in these and other pharmaceutical-related settlements.

Kinsella looked carefully at the elimination of the largest print components of the plan, *Parade* and *USA Weekend*. Kinsella also looked at the efficacy of increasing the broadcast and cable television buy. As a result, the Revised Consumer Notice Program increases the number of broadcast and cable television spots to the point at which it becomes cost inefficient to purchase additional spots. In addition, *USA Weekend* was eliminated and other print publications ranked high for consumption by prostate prescription drug users, such as the *AARP Bulletin*, were substituted. The Revised Consumer Notice Program achieves a balance between television and print, maximizing the reach of both. The Revised Consumer Notice Program achieves both the need to provide due process notice while at the same time maximizing media that traditionally drives consumer response.

C. Consumer “Easy Refund” Claim Option

The original settlement agreements and supporting materials provided consumers with an option to select a one-time flat payment of up to \$150.00 under the “Easy Refund” claim option. A consumer who elects this “Easy Refund” option does not need to provide documentation to support his or her claim but must certify under pain and penalty of perjury that he/she made percentage co-payments for Zoladex. At the hearing on July 12, 2010 the Court was concerned that \$150.00 may be inadequate in that it does not approximate the amount an average consumer with an average co-insurance payment would be forced to expend in a single year. In response to the Court’s concerns, the Settlement Agreements and supporting materials, including all consumer notices, provide

consumers the option to elect a one-time payment of up to \$400.00 for consumers who elect the “Easy Refund” option. See Revised Non-Massachusetts Settlement at Exhibit D.2, p. 5.

D. Dates For the “Heartland Period”

At the July 12, 2010 hearing, the Court inquired as to the dates used for the end of the so-called “heartland” period during which consumer’s out-of-pocket expenditures would be tripled in the calculation of their potential payment from the Settlements. The Court was concerned that the heartland period extend through the date that the federal government ceased to use AWP as a benchmark for reimbursement and that it be identical to the date for the end of the class period applied to Class 2 (so called “TPP MediGap” insurers). That change has been effectuated throughout the Revised Settlement Agreements and supporting materials, including all notice documents. Accordingly, the “heartland period” in which a consumer’s out-of-pocket expenditures will be tripled in the calculation of his/her claim extends from December 1997 to December 2004. See Revised Non-Massachusetts Settlement at Exhibit D.2, p. 6.

E. TPPs Must Provide Consumer Data by a Date Certain

At the July 12, 2010 hearing, the Court expressed concern over the time Third Party Payors would be provided to supply consumer data related to their insureds for purposes of either providing direct mail notice or calculating direct payments to consumers from TPP co-insurance data. The proposed TPP claim form provides that TPPs provide all data, including their data related to Zoladex insureds, at the same time they file their own claim and claim data. The revised Settlement Agreements now also provides that TPPs shall provide consumer data no later than the date set forth for the

filing of TPP claims. See Revised Preliminary Approval Order, Non-Massachusetts Agreement, Exhibit H, ¶15(g). The schedule proposed herewith would require TPPs to file their claim, and the related data concerning their insureds, within 60 days of the completion of direct mail notice to TPPs.

F. Proposed Schedule of Settlement Events

Class Plaintiffs propose the following schedule of events related to the settlements. The proposed schedule is based upon an assumption that preliminary approval of each of the settlements is obtained by no later than August 16, 2010. Each proposed date would apply to both the Massachusetts and Non-Massachusetts Settlements. If these dates are acceptable to the Court, Class Counsel will provide a Draft Preliminary Approval Order for each of the settlements that incorporate the dates set forth below.

EVENT	PROPOSED DATE
Direct Mail Notice to TPPs Complete	August 27, 2010
Deadline for TPP Filing of Claims, including data related to insureds	October 26, 2010
Publication Notice to Consumers (TV, Internet and Print) Complete	November 17, 2010
Direct Mail Notice to Consumers Complete	November 30, 2010
Motions In Support of Approval / Fee Petition Filed	December 15, 2010
Objections, Requests for Exclusion, Notice of Appearance Filed	December 31, 2010
Response to Objections	January 14, 2011

Final Approval Hearing (To be determined based on the Court's schedule)	January 21, 2010
Deadline for Consumers Filing of Claim	February 15, 2011

The proposed schedule allows TPPs 60 days to file their claims and the data related to their insureds. That data will be used as it is produced, on a rolling basis, to send direct mail notice to each identified consumer. Direct notice to consumers will be complete within 30 days of the deadline for receipt of the consumer data from TPPs. The dates for filing of briefs in support of the settlement and motion for attorney's fees, the filing of objections, responses to objections and a final approval hearing occur within two weeks of the preceding event. Consumers are also provided a minimum of 75 days to file a claim from the date direct mail notice to consumers is complete.

Class Counsel will make themselves available to the Court if there are additional questions or concerns related to the Settlement Agreements as revised.

DATED: August 5, 2010.

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**CO-LEAD COUNSEL FOR
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CERTIFICATE OF SERVICE BY LEXISNEXIS FILE & SERVE

Docket No. MDL 1456

I, Steve W. Berman, hereby certify that I am one of plaintiffs' attorneys and that, on August 5, 2010, I caused copies of NOTICE OF FILING REVISED SETTLEMENT AGREEMENTS, SUPPORTING MATERIAL, AND PROPOSED SCHEDULE FOR ALL SETTLEMENT EVENTS RELATED TO SETTLEMENT OF MASSACHUSETTS AND NON-MASSACHUSETTS ASTRAZENECA CLASSES TWO AND THREE to be served on all counsel of record by causing same to be posted electronically via Lexis-Nexis File & Serve.

/s/ Steve W. Berman

Steve W. Berman

EXHIBIT A

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESALE PRICE LITIGATION

MDL No. 1456

THIS DOCUMENT RELATES TO
ALL MASSACHUSETTS AND NON-
MASSACHUSETTS CLASS ACTIONS
CONCERNING ASTRAZENECA CLASSES 2 &
3

CIVIL ACTION: 01-CV-12257-PBS

Judge Patti B. Saris

AFFIDAVIT OF KATHERINE KINSELLA

I, Katherine Kinsella, being duly sworn, hereby declare as follows:

1. I am President of Kinsella Media, LLC ("KM"). KM previously presented a combined Notice Program in *In Re Pharmaceutical Industry Average Wholesale Price Litigation* in relation to both the Massachusetts and Non-Massachusetts Class 2 and 3 settlement with AstraZeneca, pending in the District of Massachusetts [Docket No. 7146, Exhibit D].
2. I submit this affidavit at the request of Plaintiffs' Counsel in response to changes in the Settlement Agreement in this case and comments made by the Court in the July 12, 2010 preliminary approval hearing related to these Settlements.
3. This affidavit is based upon my personal knowledge and upon information provided by my associates and staff. The information is of a type reasonably relied upon in the fields of advertising, media and communications.
4. At the request of Class Counsel, KM is proposing a Revised Consumer Notice Program that reflects the removal of Pulmicort Respules from the Settlement. In addition, KM has conducted a very in-depth analysis of media vehicles best suited to

reach the target audience of Zoladex users.. In creating the Revised Consumer Notice Program, as described below, KM utilized both the process of “indexing” to analyze how the target audience consumes particular media, as well as KM’s extensive prior experience with the types of media that traditionally drive responses in these and other pharmaceutical-related settlements.

5. The Revised Consumer Notice Program provides significant savings over the previous plan and relies heavily on media vehicles, in particular, *AARP Bulletin* and broadcast and cable television spots that have driven consumer responses in other cases with similar class member demographics.

Revised Consumer Notice Program

6. In response to comments made by the Court in the July 12, 2010 hearing, KM looked carefully at the elimination of the largest print components of the plan, *Parade* and *USA Weekend*. KM also looked at the efficacy of increasing the broadcast and cable television buy. As a result of our analysis, the Revised Consumer Notice Program increases the number of broadcast and cable television spots to the point at which it would become cost inefficient to purchase additional spots. In addition, *USA Weekend* is eliminated and other print publications ranked high for consumption by Prostate Prescription Drug Users are substituted. The Revised Consumer Notice Program achieves a balance between television and print, maximizing the reach of both. As a result, in my opinion, the Revised Consumer Notice Program provides both due process notice and maximizes the use of available media best suited to drive consumer response.

7. Additional print vehicles were selected to replace the reach of *USA Weekend* based on their ability to reach the target audience. However, our analysis, outlined below, reaffirmed the appropriateness of using *Parade* to secure due process notice in conjunction with the other elements of the Revised Consumer Notice Program.
8. The Revised Consumer Notice Program is designed specifically to reach consumers who fit within the relevant demographic groups without regard to Pulmicort Respules purchasers or the general public. KM chose as its target audiences:

- a. People who have taken a branded prescription for a prostate ailment

("Prostate Prescription Users")

- b. Adults above the age of 50 ("Adults 50+")

KM chose Adults 50+ as a target audience because 88% of Prostate Prescription Users are Adults 50 years of age and older. Given this high percentage, the measured delivery of media to Adults 50 years of age and older will be representative of delivery to Consumer Class Members.

9. The proposed media, a detailed description of which is attached as Exhibit A, includes advertising in national consumer magazines, a national newspaper supplement, local daily newspapers, 30-second television spots, and advertising on a medical website, www.Health.com, to reach the target audiences as outlined above.
10. In developing the Revised Consumer Notice Program, KM used "indexing" to analyze how much a target audience consumes a particular media vehicle in comparison to the general population of Adults 18 and older. KM found the following:
 - a. Prostate Prescription Users are:

- i. 212% more likely to read *AARP Bulletin* than the average adult.
- ii. 52% more likely to read *Reader's Digest* than the average adult.
- iii. 30% more likely to read *Newsweek* than the average adult.
- iv. 25% more likely to read *Parade* than the average adult.

b. Adults 50+ are:

- i. 120% more likely to read *AARP Bulletin* than the average adult.
- ii. 39% more likely to read *Reader's Digest* than the average adult.
- iii. 10% more likely to read *Newsweek* than the average adult.
- iv. 24% more likely to read *Parade* than the average adult.

11. KM included *Parade* in the Revised Consumer Notice Program due to the high consumption of the magazine by Adults 50+. Based on the 2010 Spring GfK MRI¹ study, 37.1 million adults 50 years and older read an average issue of *Parade*. In addition, over fifty percent of *Parade*'s readership comes from Adults 50+.

12. In other cases involving pharmaceutical drugs, we have seen where the inclusion of TV spots can increase response. For example, in *In Re: Bextra and Celebrex Marketing, Sales Practices, and Product Liability Litigation*, which involved purchasers of the drugs Bextra and Celebrex, in the two weeks that TV advertising was used, the number of unique visitors to the Settlement website increased by 50% over the previous four weeks of print advertising. Calls to the Settlement toll-free hotline increased by 480% over the previous four weeks. Seventy percent of Celebrex users are 45 years of age and older.

¹ GfK MRI is a nationally accredited media and marketing research firm that provides syndicated data on audience size, composition, and other relevant factors pertaining to major media including broadcast, magazines, newspapers, and outdoor advertising. GfK MRI provides a single source measurement of major media, products, services, and in-depth consumer demographic and lifestyle/psychographic characteristics.

13. *AARP Bulletin* has been shown to have a similar increase in responses when used to target individuals who used a high-cholesterol brand prescription, of which almost 70% are over the age of 55. In *In Re Tricor Indirect Purchaser Antitrust Litigation*, calls to the Settlement toll-free hotline increased by 25% once *AARP Bulletin* reached its full circulation.

14. For the purpose of evaluating the strength and efficiency of the media, the national newspaper supplement, national consumer magazines, television spot advertising and Internet advertising were measured against the target audiences to establish the estimated *reach*² of the media program and the estimated *frequency*³ of exposure to the media vehicles.

- a. The print plan will deliver an estimated 71.9% reach against Prostate Prescription Users with an estimated average frequency of 1.6⁴ and an estimated 65.5% reach against Adults 50+ with an estimated average frequency of 1.5.
- b. The Revised Consumer Notice Program, including print vehicles, television and Internet will deliver an estimated 80.18% reach against Adults 50+ with an estimated average frequency of 2.0. Because the reach of the print plan against Prostate Prescription Users is significantly higher than for Adults 50+, the overall reach of print, television and Internet can be expected to deliver a higher reach against Prostate Prescription Users than 80.18%.

² Reach is the estimated percentage of a target audience reached through a specific media vehicle or combination of media vehicles.

³ Frequency is the estimated average number of opportunities an audience member has to see the notice.

⁴ The contribution of television and Internet reach is not counted against this target as we can only buy these media against age and gender demographics.

Conclusion

15. It is my opinion the Revised Consumer Notice Program is fully compliant with Rule 23 of the Federal Rules of Civil Procedure. The program is stronger than the bifurcated program previously submitted which attempted to reach two diverse target audiences consisting of Zoladex users and Pulmicort Respules purchasers. The Revised Consumer Notice Program addresses the Court's concerns about over utilization of large publications and maximizes the use of media vehicles, such as TV ads and *AARP Bulletin* that historically drive consumer response. At the same time the Revised Consumer Notice Program expends less money than the original program.

I declare under penalty of perjury that the foregoing is true and correct. If called as a witness, I could and would competently testify thereto.

Katherine Kinsella
Katherine Kinsella

August 3, 2010
Date

EXHIBIT A

Notice Program Estimate**AWP (AstraZeneca Settlement) - Zolodex w/ Parade**

7/28/2010

**Target Audience(s)**

- People who have taken a branded prescription for a prostate ailment ("Prostate Prescription Users")
- Adults above the age of 50 ("Adults 50+")

Paid Media Components**Print Media****Magazine(s)**

	Circulation	Unit Type/Size	Insertions
<i>AARP Bulletin</i>	24,000,000	2/3 Page (5.75" x 10.56")	1
<i>Newsweek</i>	1,500,000	Full Page (7" x 10")	1
<i>Reader's Digest</i>	5,500,000	Full Page (4.75" x 6.75")	1

Newspaper(s)

<i>All Daily Newspaper (Massachusetts - 30 papers)</i>	1,063,372	1/4 page	1
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Newspaper Supplement(s)

<i>Parade</i>	32,400,000	Half Page (4.375" x 9.25")	1
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Broadcast Media**TV**

	GRPs (gross rating points)	Spot Length	Estimated Frequency
<i>Broadcast Network/Cable</i>	66	30 sec.	59

Online Media**Web**

	Ad Type/Size	Estimated Impressions
<i>Health.com Integrated Solutions</i>	728 x 90 or 300 x 250	1,000,000

Specifications regarding online ads:

Activity will appear on pages related to Prostate Cancer within the Health.com network.

Other Program Components

Misc. Expenses: Flat fee (shipping/copying/telecom)
 Production and Distribution: Print Ad
 Production and Distribution: TV Spot
 Production and Distribution: Web Ad
 Tearsheet scanning
 Sponsored Keyword Search Ads
 Notice Materials: Drafting/Editing

Estimated Program Delivery

- The print plan will deliver an estimated 65.5% reach against Prostate Prescription Users with an average frequency of 1.5. The contribution of TV and Internet reach is not counted against this target as we can only buy these media against age and gender demographics.

- The plan will deliver an estimated 80.18% reach against Adults 50+ with an average frequency of 2.0.

Important Terms:

1. Rates reported herein are confidential and proprietary and may not be disclosed to any parties without prior approval from Kinsella Media, LLC ("KM").
2. Upon receiving final ad copy, KM will negotiate final advertising rates. Advertising rates are set by the individual media properties and are subject to space availability and may change without notice.

3. If the client has not yet provided KM with a final version of the Summary Notice or a word count, ad costs are based on a Summary Notice of approximately 700 words. A longer Summary Notice may require larger ad sizes and therefore entail higher costs. If KM has received the final Summary Notice text, the estimate is based on actual word count.
4. If the estimate includes a press release and the client has not yet provided KM with a final version of the release or a word count, the estimated press release cost is based on a release of up to 500 words. A longer press release will entail higher costs. If KM has received the final press release text, the estimate is based on actual word count.